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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/936,747 | 02/15/2002 | Christian Kropf | CU-2655 RJS | 8969 |

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06/03/2004

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EXAMINER

LAMM, MARINA

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/936,747 | Applicant(s) KROPF ET AL. | |
| | Examiner Marina Lamm | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-25, 28, 29, 31 and 32 is/are rejected.
- 7) ☒ Claim(s) 26, 27 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the amendment filed 4/16/04. Claims pending are 17-32. Claims 17, 24, 29 and 31 have been amended.

Allowable Subject Matter

1. The indicated allowability of claims 17-23 is withdrawn in view of the newly discovered reference(s) to Lehmann et al. Rejections based on the newly cited reference(s) follow.
2. Claims 26, 27 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 17, 19, 21-25, 28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann et al. (US 6,143,883) either alone or in view of Donzis (US 5,705,184).

Lehmann et al. teach topical compositions containing water-soluble β -(1,3)-glucan suspended in a carrier. See col. 5, lines 5-39. The suitable carriers include gel carrier. See col. 5, line 25. The glucan of Lehmann et al. is prepared by enzymatically

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digesting or cleaving the large water-insoluble molecules of glucan, fractionating the resulting product and lyophilizing the water-soluble fraction. See col. 5, Example 1. The glucan of Lehmann et al. is inherently free from repetitive β -(1,6) linkages because it has been enzymatically treated with cellulase and it is water-soluble. The reference does not explicitly teach the particle size of the lyophilized glucan. However, there appears to be no criticality in the particle size since the prior art recognizes and obtains the same results, i.e. "water-soluble glucan is more efficacious as a dermatological agent". See col. 5, lines 14-20, 29-35. Therefore, the determination of optimal particle size of glucan by routine experimentation is obvious to one of ordinary skill in this art. One having ordinary skill in the art would have been motivated to do this in order to obtain the desired therapeutic effect of the glucan. No unexpected properties are seen that would demonstrate an unusual result over the generic teachings of the reference. Alternatively, Donzis teaches that glucans having a particle size of about 200 nm or less "stay better suspended in the vase carrier...thereby making the glucan particles less likely to fall out of the suspension prior to use." See col. 2, lines 55-58; col. 3, lines 40-45. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Lehmann et al. such that to employ β -(1,3)-glucan having a particle size of 200 nm or less. One having ordinary skill in the art would have been motivated to do this to obtain glucan suspensions having enhanced stability as suggested by Donzis.

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With respect to Claims 21 and 32, the reference does not explicitly teach the concentration of the glucan in the compositions. However, it is the Examiner's opinion that the determination of optimal or workable concentration of glucan by routine experimentation is obvious absent showing of criticality of the claimed concentration. One having ordinary skill in the art would have been motivated to do this to obtain the desired therapeutic properties of the composition.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann et al. either alone or in view of Engstad et al. (WO 95/30022).

Lehmann et al. applied as above. Lehmann et al. do not teach that glucans are obtained from yeast cells of the family *Saccharomyces* as claimed herein. However, Lehmann et al. teach that glucans can be isolated from plants and microorganisms. See col. 1, lines 13-14. There appears to be no criticality as to the particular source of the glucan since the glucans isolated from either source show the same immunomodulating effect. See col. 1, lines 15-39. Alternatively, Engstad et al. teach β -(1,3)-glucan isolated from yeast cells of the family *Saccharomyces*. See Abstract. The glucan of Engstad et al. "is characterized by its enhanced activity in effecting stimulation of the immune system." See p. 2, lines 11-17. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Lehmann et al. such that to employ β -(1,3)-glucan isolated from yeast cells of the family *Saccharomyces*. One having ordinary skill in the art would have been motivated

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to do this to obtain compositions having enhanced immunostimulating activity as suggested by Engstad et al.

6. Claims 20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann et al. either alone or in view of Donzis and further in view of Ofuchi et al. (US 4,333,927).

Lehmann et al. or Lehmann et al. in view of Donzis applied as above. While teaching gel carriers, Lehmann et al. do not explicitly teach PVA or polyethylene glycol of the instant claims. However, Ofuchi et al. teach PVA or polyethylene glycol as conventional gelatinizers for topical compositions. See col. 3, lines 27-29. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ PVA or polyethylene glycol for the gel compositions of Lehmann et al. One having ordinary skill in the art would have been motivated to do this to gelling as suggested by Ofuchi et al.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,376,173; US 5,688,775.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ml

5/19/04

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